Remarks

Claims 41-82 and 85 are pending in the subject application. Applicant gratefully acknowledges the Examiner's indication that claim 70 is free of the prior art and allowed. By this Amendment, Applicant has canceled claims 49-53, 72, 73, 81, 82, and 85. Claims 83 and 84 were canceled by Applicant's Amendment dated July 14, 2004, although the cancellation was not noted in the Advisory Action. Accordingly, claims 41-48, 54-71, and 74-80 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

In the outstanding Advisory Action, the Examiner indicates that the priority claim presented in Applicant's amendment to the "Cross-Reference to Related Applications" section does not comply with the rules for obtaining priority in a National Stage Application filed on or after November 29, 2000 and states that the filing date of the instant application is December 27, 2000. Applicant respectfully asserts that the priority claim submitted in the Amendment dated July 14, 2004 and submitted herewith does comply with 37 CFR 1.78. In this respect, Applicant refers the Examiner to 37 CFR 1.78(a)(2)(ii)(c) which states that the time periods set forth in the rule for making a domestic priority claim do **not** apply to an application that is a "nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000." The key element of the rule is that the international application, **not** the national stage application, must have been filed before November 29, 2000. The subject application entered the national stage from International application Serial No. PCT/US99/09366 which was filed on April 29, 1999, which is a date considerably before November 29, 2000. Moreover, it is irrelevant under the rule that the date of compliance of the national stage application with 35 USC §371 was after November 29, 2000. The rule does not require that the date of compliance with 35 USC §371 be prior to November 29, 2000. Thus, the time periods set forth in the rules for making a priority claim do not apply to the subject application and a petition to accept a delayed claim for priority is not required.

Accordingly, Applicant respectfully maintains the claim to the benefit of the effective filing date of U.S. application Serial No. 08/919,421 (hereinafter the '421 application). The Examiner indicates in the Advisory Action that the subject application is not entitled to a claim of priority to the '421 application on the grounds that the '421 application (and the 60/025,800 provisional

application) "were not found to be a basis for priority in the PCT application" during the international phase of the subject application and, therefore, priority cannot be granted by the U.S. Patent Office. The Examiner also states in the Advisory Action that "the filing dates for both US applications were greater than one year prior to the filing date of PCT application US99/09366." Applicant again notes that the Examiner appears to assume that Applicant has made a claim of priority to the '421 application and the '800 application under the Paris Convention Treaty. However, Applicant is **not** making a claim of priority to the '421 application or the '800 application under the Paris Convention. Applicant is claiming the benefit of the filing date of an earlier application under **35 USC §120** of the United States Patent Statute; nowhere in Applicant's comments in the January 23 Amendment regarding the claim to the '421 application did Applicant refer to a "claim of priority." A claim of priority under the Paris Convention and a claim for the benefit of a filing date under 35 USC §120 are not related; they are separate and distinct issues. Because Applicant is not making a claim of priority to the '421 application under the Paris Convention Treaty, the rules associated with the Paris Convention regarding a claim of priority to an earlier application are not pertinent in this matter. The "one year" time period for claiming priority under the Paris Convention is not applicable to the instant matter. The relevant statute and rules are 35 USC §120 and 37 CFR 1.78, respectively. The Examiner's attention is again directed to MPEP 1893.03(c), relevant portions of which are reprinted below.

> **A national stage application may include a priority claim** under 35 U.S.C. 119(e), or 120 and 365(c) **to a prior U.S. national application** or under 35 U.S.C. 120 and 365(c) to a prior international application designating the U.S. The conditions for according benefit under 35 U.S.C. 120 are as described in MPEP § 201.07, § 201.08, and § 201.11 and are similar regardless of whether the U.S. national application is a national stage application *>submitted< under 35 U.S.C. 371 or a national application filed under 35 U.S.C. 111(a).
>
> **In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 120 and 365(c) of a prior filed copending nonprovisional application** or prior filed copending international application designating the United States of America, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(1) through 37 CFR 1.78(a)(3). **The prior nonprovisional application or international application must name as an inventor at least one inventor named in the later filed international**

> **application "X"** and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112. **The national stage application must contain a reference to the prior nonprovisional or international application** (either in an application data sheet (37 CFR 1.76) or in the first sentence of the specification), identifying it by application number (series code and serial number) or international application number and international filing date and indicating the relationship of the applications.
>
> **A prior filed nonprovisional application is copending with the national stage application if the prior U.S. national application was pending on the international filing date of the national stage application.** (emphasis added)

As the Examiner is aware, U.S. Application No. 08/919,421 was filed August 27, 1997 and issued as U.S. Patent No. 5,916,751 on June 29, 1999, and claims the benefit under 35 USC §119(e) of U.S. provisional Application No. 60/025,800, filed August 27, 1996; thus, the effective filing date of the '421 application is August 27, 1996. As noted above, Applicant's benefit claim to the '421 application is made under 35 USC §120. Applicant refers the Examiner to the "Cross-Reference to Related Applications" section at page 1, lines 6-9, of the subject specification. Applicant's benefit claim (again, not a claim of priority under the Paris Convention Treaty) to the '421 application was present in the subject application as filed. Although there may have been a punctuation error in the "Cross-Reference to Related Applications" section set forth at page 1, lines 3-9, of the subject specification, it has been clear from the filing of the subject application that Applicant intended that the subject application was a continuation-in-part application of the '421 application. In accordance with MPEP 1893.03(c), Applicant notes that as long as the '421 application was:

1) co-pending with PCT application No. PCT/US99/09366 (filed April 29, 1999), which it was; and
2) shared at least one co-inventor with the subject application, which it does; and
3) contained a reference to the prior nonprovisional application (the '421 application) identifying it by application number, which it did and does;

then the subject application (a national stage of PCT application No. PCT/US99/09366) can claim the benefit of the filing date of the '421 application, regardless of whether priority to the '421 application was granted under the PCT and regardless of whether the application was filed under 35

USC §371 or 35 USC §111 (as noted above in the text from MPEP 1893.03(c), an application can be filed under 35 USC §371 and still claim the benefit of an earlier filed U.S. application, *e.g.*, as a continuation-in-part of the earlier filed application). Applicant also notes that the subject application currently names Siamak Tabibzadeh as the inventor of the claimed subject matter and that Siamak Tabibzadeh is also named as an inventor on each of the applications listed in the "Cross-Reference to Related Applications" section.

To summarize, the subject application is a national stage application of PCT application No. PCT/US99/09366 which was filed April 29, 1999. Thus, April 29, 1999 is the actual filing date of the subject application (the Examiner should not confuse the actual filing date of a national stage application (in this case, April 29, 1999) with the date of compliance with 35 USC §371 (in this case December 27, 2000); they are two entirely different dates. The '421 application was pending from August 27, 1997 to June 29, 1999; thus, the subject application was pending during the pendency of the '421 application. In addition, Siamak Tabibzadeh is named as an inventor on both the subject application and the '421 application. The subject application also includes a reference to the '421 application and indicated its relationship with the '421 application (*i.e.*, a "Continuation in Part"). As can be understood from the above, the subject application has continuity of pendency and inventorship with the '421 application and has continuously had a cross-reference to the '421 application in the specification. Therefore, the subject application is entitled to claim the benefit of the '421 application under 35 USC §120.

At Section 2 of the Advisory Action, the Examiner asserts that the "only priority granted [to the subject application] was to United States Provisional Application No. 60/025,800 filed August 27, 1996." At Section 4 of the Action, the Examiner asserts that "priority claimed through a Provisional Application 60/083,418 is not provided for, nor permitted." Applicant has clarified that the subject application is **not** claiming priority through provisional application 60/083,418. In the original "Cross-Reference" section, use of "This application" clearly means the subject application (application No. 09/674,254). Although there is a period at the sentence after "60/083,418" in the "Cross-Reference" section, it is clear that the "Cross-Reference" section intended that the subject application (*i.e.*, "This application . . .") is a "Continuation in Part of application Serial No. 08/919,421 . . .." Thus, it is clear that Applicant was not claiming priority to the 08/919,421

application through the 60/083,418 provisional application; rather Applicant intended that the subject application is a "continuation-in-part" of the '421 application. This is the only way to read the priority claim that makes sense given that a provisional application cannot be a "continuation-in-part" of a non-provisional application.

Applicant has amended the "Cross-Reference to Related Applications" section of the subject application to correct the punctuation error in the benefit claim to clarify that the subject application is a continuation-in-part of the '421 application. Applicant respectfully asserts that this amendment should be permitted because the subject specification already included a cross-reference to the '421 application (and U.S. provisional application Serial No. 60/025,800) and, as noted above, because the subject application entered the national stage from International patent Application No. PCT/US99/09366 which was filed April 29, 1999, which is well before the November 29, 2000 date specified in 37 CFR 1.78(a)(ii)(C) (thus, the time period rules do not apply to the application). Entry of the "Cross-Reference to Related Applications" amendment is respectfully requested. If the Examiner requires further clarification regarding Applicant's claiming the benefit of the filing date of the '421 application under 35 USC §120, Applicant respectfully requests that the Examiner contact Applicant's undersigned representative to resolve this issue.

At section 10 of the Office Action, the Examiner has indicated that claims 81-85 are withdrawn from further consideration as being directed to a non-elected invention. The Examiner asserts that claims 81-85 recite "components contained in compositions not previously considered on the record . . .." As indicated above, claims 83 and 84 were canceled by Applicant's Amendment dated July 14, 2004. Applicant respectfully asserts that claims 81, 82, and 85 are directed to the elected invention, as was discussed in Applicant's Amendment dated July 14, 2004, and should have been considered in the examination of the subject application. However, by this Amendment, Applicant has also **canceled** claims 81, 82, and 85 solely to expedite prosecution of the subject application.

Claims 72 and 73 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. In addition, claims 72 and 73 are rejected under 35 USC §112, second paragraph, as indefinite on the grounds that the claims do not recite what components are in the composition administered to the female animal in the claimed methods. The Examiner asserts that

the composition being administered is described by function only, and does not recite any specific reagent components or elements with the recited biological function. Applicant respectfully asserts that the claims are enabled by the subject specification and are not indefinite. However, in order to expedite prosecution, Applicant has **canceled** claims 72 and 73 by this Amendment. Thus, the rejections are now moot. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, first paragraph, and under 35 USC §112, second paragraph, is respectfully requested.

Claims 41-69 and 71 are rejected under 35 USC §102(b) as anticipated by Tabibzadeh *et al.* (U.S. Patent No. 5,916,751, which issued from the '421 application). In addition, claims 74-80 are rejected under 35 USC §103(a) as obvious over Tabibzadeh *et al.* (U.S. Patent No. 5,916,751). In the Office Action dated October 23, 2003, the Examiner asserted that the Tabibzadeh *et al.* patent discloses detecting or diagnosing endometrial irregularity in a female, including the screening of endometrial tissue or blood for abnormal levels of *ebaf* nucleic acid or proteins. Applicant notes that in the October 23, 2003 Office Action, the Examiner relied on the incorporated Kothapalli *et al.* reference as teaching that *ebaf* expression is associated with endometrial bleeding (however, Applicant notes that the Kothapalli *et al.* reference was not explicitly indicated as being relied on in the rejections). The Examiner also stated that the Tabibzadeh *et al.* patent discloses the utilization of nucleic acid detection and protein detection kits for the determination of *ebaf* nucleic acid expression and/or ebaf protein/peptide biological activity in a biological sample. In regard to the obviousness rejection, the Examiner concluded that it would have been obvious to the ordinarily skilled artisan to formulate the necessary reagents for the determination, detection or diagnosis of an ebaf-related condition in view of the teachings of the Tabibzadeh *et al.* patent. Applicant assumes, in view of the rejection under 35 USC §102(b), that the Tabibzadeh *et al.* patent relied upon for the §103 rejection is being applied as a §102(b) reference by the Examiner for purposes of the §103 rejection.

In response to Applicant's Amendment submitted January 23, 2004, the Examiner rejected Applicant's traversal of the rejections on the grounds that Applicant's priority claim to the '421 application "has not been granted by either the PCT searching authority, nor the US-PTO" and, therefore, the Tabibzadeh *et al.* patent is "appropriately applied as prior art." Applicant respectfully traverses the rejections under 35 USC §102(b) and 35 USC §103(a).

As an initial matter, Applicant notes that the subject application (even without the benefit of the filing date of the '421 application) has an actual filing date of April 29, 1999. The Tabibzadeh *et al.* patent (U.S. Patent No. 5,916,751) issued on June 29, 1999 which is after the April 29, 1999 filing date of the subject application. A reference only qualifies as prior art under 35 USC §102(b) if the reference was published more than one year before the filing date of a patent application. Thus, the Tabibzadeh *et al.* patent does not qualify as prior art under 35 USC §102(b)/35 USC §103 against the subject application. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102(b) and 35 USC §103(a) is respectfully requested.

Although the rejections in the Office Action are under 35 USC §102(b)/103, Applicant also submits the following comments in the event the Examiner would make a rejection under 35 USC §102(e). Applicant hereby incorporates the remarks presented herein in regard to Applicant's claim to the benefit of the filing date of the '421 application for the subject application. As noted above, the subject application claims the benefit of the effective filing date of the '421 application (*i.e.*, August 27, 1996, the filing date of provisional application No. 60/025,800) under 35 USC §120. The Tabibzadeh *et al.* patent applied under the §102/§103 rejections issued from the '421 application. Applicant further notes that the Kothapalli *et al.* reference was apparently published sometime in or around May 1997 which is after the August 27, 1996 filing date of the 60/025,800 provisional application. In view of Applicant's claim to the benefit of the effective filing date of the '421 application, August 27, 1996, Applicant respectfully asserts that the Tabibzadeh *et al.* patent that issued from the '421 application is not effective prior art against the subject application under 35 USC §102(e).

Claims 49-51 are rejected under the judicially created doctrine of "obviousness-type" double patenting over claims 1 and 7 of U.S. Patent No. 6,294,662. Applicant respectfully asserts that the claims are not obvious over the cited patent. However, as noted above, claims 49-51 have been **canceled** by this Amendment, thereby rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 72 is rejected under the judicially created doctrine of "obviousness-type" double patenting over claims 1, 5, 14, and 15 of U.S. Patent No. 6,649,588 (hereinafter the '588 patent). Applicant respectfully asserts that claim 72 is not obvious over claims 1, 5, 14, and 15 of the cited

patent. The '588 patent has a filing date of October 5, 2000 and issued on November 18, 2003. The subject application is a U.S. national stage application of PCT application No. PCT/US99/09366, filed April 29, 1999. Thus, the '588 patent is not prior art to the subject application. Moreover, claim 1 of the '588 patent is directed to contacting tissue expressing TGF-β with an *ebaf* protein to inhibit TGF-β activity whereas claim 72 of the subject application is directed to decreasing expression or activity of an *ebaf* protein in an animal in order to increase the fertility of the animal. Applicant notes that claims 5, 14, and 15 of the '588 patent all depend directly or indirectly from claim 1. The claims in the '588 patent do not teach or suggest anything regarding decreasing *ebaf* activity to increase fertility. Accordingly, Applicant respectfully asserts that claim 72 is not obvious over the claims of the '588 patent. However, as noted above, claim 72 has been **canceled** by this Amendment, thereby rendering the rejection moot. Reconsideration and withdrawal of the rejection is respectfully requested.

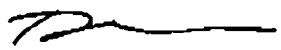
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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